

Complete Summary

GUIDELINE TITLE

Migraine.

BIBLIOGRAPHIC SOURCE(S)

Migraine. Philadelphia (PA): Intracorp; 2005. Various p. [21 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the [FDA Web site](#) for more information.

Additional Notices

- On July 19, 2006, the FDA notified healthcare professionals and consumers of new safety information regarding taking medications used to treat migraine headaches (triptans) together with certain types of antidepressant and mood disorder medications, selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs). A life-threatening condition called serotonin syndrome may occur when triptans are

- used together with a SSRI or a SNRI. See the [FDA Web site](#) for more information.
- On April 25, 2005 the FDA notified healthcare professionals and patients that cases of breathing problems, some causing death, have been reported to the FDA when Promethazine HCl (marketed as Phenergan) was used in children less than two years old. Parents and caregivers should also be careful and get a doctor's advice about giving promethazine HCl in any form to children age two and older. The labeling on all products, brand name and generic, has been changed to reflect these strengthened warnings. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Migraine without aura
- Migraine with aura
- Chronic migraine

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology
Preventive Medicine

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, prevention, and management of migraine that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with suspected or known migraine

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
 - Computerized tomography (CT) or magnetic imaging (MI) only in patients with atypical or changing headache patterns, a history of seizures, or focal neurologic signs or symptoms

Management/Treatment/Prevention

1. Nonsteroidal anti-inflammatory drugs (NSAIDs)
2. Acetaminophen-aspirin-caffeine combination
3. Serotonin agonists (triptans)
4. Antiemetics
5. Neuroleptics
6. Corticosteroids
7. Opiates
8. Prophylactic regimens, including
 - Calcium channel blockers
 - Beta blockers
 - Ergots
 - Tricyclic antidepressants
 - Monoamine oxidase inhibitors (MAOI)
 - Selective serotonin re-uptake inhibitors
 - Serotonin antagonists
 - Anticonvulsants
9. Referral to specialists

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or

the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Migraine without aura - must have at least 5 attacks that fulfill all of the following criteria:
 - Lasting from 4 to 72 hours (untreated or unsuccessfully treated)
 - Having at least two of the following characteristics:
 - Unilateral location
 - Pulsating quality
 - Moderate or severe intensity (preventing daily activities)
 - Aggravation by walking stairs or similar activity
 - During the headache, experiencing at least one of the following:
 - Nausea and/or vomiting

- Photophobia and phonophobia
- Migraine with aura - must have at least two attacks that fulfill at least three of the four following characteristics:
 - One or more fully reversible aura symptoms indicating focal cerebral cortical and/or brain stem dysfunction
 - At least one aura symptom develops gradually over more than 4 minutes or two or more symptoms occur in succession
 - No aura symptom lasts more than 60 minutes; if more than one aura symptom is present, accepted duration is proportionally increased
 - Headache follows aura with a free interval of less than 60 minutes (it may also begin before or simultaneously with the aura)
- Most headache specialists advocate patients maintain a "headache journal" in order to document symptoms as they occur, and to encourage self-management strategies for these individuals.

Objective Findings

- No other evidence to suggest the headache arises from head trauma, vascular disorders, non-vascular intracranial disorders, substance withdrawal, infection, metabolic disorders, cranial structures (teeth, sinuses, etc.), or cranial neuralgias

Diagnostic Tests

- A summary statement from the American Academy of Neurology (AAN) put forth the following recommendation:
 - In adult patients with recurrent headaches that have been defined as migraine, including those with visual aura, with no recent change in pattern, no history of seizures, and no other focal neurologic signs or symptoms, the routine use of neuroimaging is not warranted.
 - In patients with atypical or changing headache patterns, a history of seizures, or focal neurologic signs or symptoms, computerized tomography (CT) or magnetic imaging (MI) may be indicated.

Differential Diagnosis

- Tension headaches
- Cluster headaches
- Head trauma
- Subarachnoid hemorrhage
- Intracranial hematoma
- Hypertensive headache (headache associated with strongly elevated blood pressure)
- Arteritis (temporal)
- Depression
- Venous thrombosis
- Central nervous system (CNS) infection (meningitis, encephalitis)
- Systemic infection (viral, bacterial illness)
- Neoplasm
- Carbon monoxide poisoning
- Increased intracranial pressure

- Headaches associated with cranial structure (sinuses, teeth, eyes, especially glaucoma)
- Temporomandibular (TMJ) joint headaches
- Cranial neuralgias (trigeminal, etc.)
- Post-herpetic neuralgia
- Headache associated with the consumption or withdrawal of certain substances
- Metabolic disorders (hypoglycemia, dialysis, hypoxia)
- Headaches of idiopathic etiology:
 - Ingestion of cold food/drink
 - Associated with chronic coughing, excessive vomiting

Treatment Options

- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., Anaprox, Naprosyn, Oruvail)
- Acetaminophen-aspirin-caffeine combination (non-prescription combination, e.g., Excedrin)
- Serotonin agonists (e.g., Migranal, D.H.E. 45, Imitrex, Relpax)
- Antiemetics (e.g., Compazine, Inapsine, Phenergan)
- Neuroleptics (e.g., Antivert, Dramamine)
- Corticosteroids (e.g., Cortisone)
- Opiates (much less effective than the above agents)
- Prophylactic regimens
 - Calcium channel blockers (e.g., Cardizem, Isoptin)
 - Beta blockers (e.g., atenolol, metoprolol)
 - Ergots (e.g., Ergostat, Ercaf)
 - Tricyclic antidepressants (e.g., Amitriptyline, Doxepin)
 - Monoamine oxidase inhibitors (MAO) (e.g., Marplan, Eldepry)
 - Selective serotonin re-uptake inhibitors
 - Serotonin antagonists (e.g., Cafergot, Cafatine, Cafetrate)
 - Anticonvulsants (e.g., Phenobarbital, Valproic Acid)
- Caution must be exercised in patients with comorbid medical conditions, due to potential drug interactions between their other medications and those for prevention/relief of headaches

Duration of Medical Treatment

- Medical - Optimal: 2 day(s), Maximal: 7 day(s)

Additional information regarding primary care visit schedules, referral options, and specialty care is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving pain without symptoms of vomiting or photosensitivity
- Resolving pain with symptoms of vomiting or photosensitivity

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, prevention, and management of migraine that assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

Caution must be exercised in patients with comorbid medical conditions, due to potential drug interactions between their other medications and those for prevention/relief of headache.

CONTRAINDICATIONS

CONTRAINDICATIONS

Triptans should not be used in a patient who has uncontrolled hypertension or basilar or hemiplegic migraine or who is at risk for heart disease.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Migraine. Philadelphia (PA): Intracorp; 2005. Various p. [21 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

GUIDELINE DEVELOPER COMMENT

Not applicable

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 19, 2005. The information was verified by the guideline developer on September 2, 2005. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Promethazine HCl. This summary was updated by ECRI on August 29, 2006, following the U.S. Food and Drug Administration advisory on Triptans, SSRIs, and SNRIs.

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